

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Hill et al.

Serial No.: To Be Assigned

Filed: Concurrently Herewith

For: *NOVEL ESTROGENIC COMPOUNDS*

Date: July 23, 2003

Mail Stop PATENT APPLICATION

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

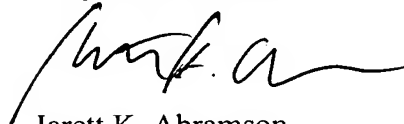
INFORMATION DISCLOSURE STATEMENT

Sir:

Attached is a list of documents on form PTO-1449. Items listed on the PTO-1449 were cited in parent application Serial No. 09/800,614, filed March 8, 2001. Since the benefit of this application is claimed under 35 U.S.C. §120, no copies need to be furnished in accordance with 37 C.F.R. §1.98(d); however, copies will be furnished on request. It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. §1.97 and Section 609 of the MPEP.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to our Deposit Account No. 50-0220.

Respectfully submitted,



Jarett K. Abramson

Registration No. 47,376

Myers Bigel Sibley & Sajovec, LLP

USPTO Customer Number: **20792**

Post Office Box 37428

Raleigh, NC 27627

Tel (919) 854-1400

Fax (919) 854-1401

CERTIFICATE OF EXPRESS MAILING

Express Mail Label No. EV 353608697 US

Date of Deposit: July 23, 2003

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop PATENT APPLICATION, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450



Clara R. Board

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)				Attorney Docket Number: 8789-16CT		Serial No. to be assigned	
				Applicants: Hill et al.			
				Filing Date: concurrently herewith		Group to be assigned	
U. S. PATENT DOCUMENTS							
Examiner Initial	Serial No.	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1.	3,230,142	1/18/66	Spero	167	55	
	2.	3,487,152	12/30/69	Carstensen et al.	424	240	
	3.	3,502,772	3/24/70	Ijzerman	424	239	
	4.	3,568,828	3/9/71	Lerner	206	42	
	5.	3,591,688	7/6/71	Jones et al.	424	239	
	6.	3,639,600	2/1/72	Hendrix	424	242	
	7.	3,733,407	5/15/73	Segre	424	239	
	8.	3,795,734	3/5/74	Rocheffort	424	238	
	9.	3,836,651	9/17/74	Rudel et al.	424	239	
	10.	3,813,418	05/28/74	Hofmeister et al.	260	397.4	
	11.	3,932,635	1/13/76	Segre	424	238	
	12.	3,939,264	2/17/76	Lachnit-Fixson	424	239	
	13.	3,942,641	3/9/76	Segre	206	534	
	14.	3,957,982	5/18/76	Lachnit-Fixson et al.	424	238	
	15.	3,969,502	7/13/76	Lachnit-Fixson	424	238	
	16.	4,027,019	5/31/77	Shroff	424	238	
	17.	4,066,757	1/3/78	Pasquale	424	243	
	18.	4,071,623	1/31/78	van der Vies	424	238	
	19.	4,145,416	3/20/79	Lachnit-Fixson et al.	424	238	
	20.	4,147,783	4/3/79	van der Vies	424	243	
	21.	4,154,820	5/15/79	Simoons	424	175	
	22.	4,210,644	7/1/80	Ewing et al.	424	239	
	23.	4,259,325	3/31/81	Prezewowsky et al.	424	238	
	24.	4,291,028	9/22/81	Vorys	424	238	
	25.	4,292,315	9/29/81	Vorys	424	240	

EXAMINER
 *EXAMINER

DATE CONSIDERED

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)					Attorney Docket Number: 8789-16CT		Serial No. to be assigned
					Applicants: Hill et al.		
					Filing Date: concurrently herewith		Group to be assigned
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	26.	4,315,925	2/16/82	Hussain et al.	424	239	
	27.	4,327,725	5/4/82	Cortese et al.	128	260	
	28.	4,378,356	3/29/83	De Jager	424	238	
	29.	4,383,993	5/17/83	Hussain et al.	424	239	
	30.	4,390,531	6/28/83	Edgren	424	239	
	31.	4,425,339	1/10/84	Pitchford	424	239	
	32.	4,512,986	4/23/85	Reel et al.	514	170	
	33.	4,530,839	7/23/85	Pasquale	514	171	
	34.	4,544,554	10/1/85	Pasquale	514	170	
	35.	4,616,006	10/7/86	Pasquale	514	170	
	36.	4,621,079	11/4/86	Lachnit-Fixson et al.	514	170	
	37.	4,628,051	12/9/86	Pasquale	514	170	
	38.	4,738,957	4/19/88	Laurent et al.	514	182	
	39.	4,756,907	7/12/88	Beck et al.	424	85	
	40.	4,762,717	8/9/88	Crowley, Jr.	424	425	
	41.	4,764,378	8/16/88	Keith et al.	424	435	
	42.	4,783,337	11/8/88	Wong et al.	424	468	
	43.	4,816,257	3/28/89	Buster et al.	424	448	
	44.	4,816,258	3/28/89	Nedberge et al.	424	448	
	45.	4,826,831	5/2/89	Plunkett et al.	514	170	
	46.	4,855,305	8/8/89	Cohen	514	171	
	47.	4,900,734	2/13/90	Maxson et al.	514	171	
	48.	4,914,089	4/3/90	Tax	514	170	
	49.	4,921,843	5/1/90	Pasquale	514	170	
	50.	4,962,098	10/9/90	Boissonneault	514	170	
	51.	4,977,147	12/11/90	Jungblut et al.	514	171	

EXAMINER _____
 *EXAMINER

DATE CONSIDERED _____

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)				Attorney Docket Number: 8789-16CT		Serial No. to be assigned	
				Applicants: Hill et al.			
				Filing Date: concurrently herewith		Group to be assigned	
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	52.	5,006,345	4/9/91	Lang	424	467	
	53.	5,010,070	4/23/91	Boissonneault	514	171	
	54.	5,043,331	8/27/91	Hirvonen et al.	514	179	
	55.	5,089,482	2/18/92	Hermens et al.	514	58	
	56.	5,098,714	3/24/92	Wright et al.	424	473	
	57.	5,108,995	4/28/92	Casper	514	170	
	58.	5,130,137	7/14/92	Crowley, Jr.	424	422	
	59.	5,183,814	2/2/93	Dukes	514	170	
	60.	5,200,197	4/6/93	Wright et al.	424	473	
	61.	5,208,225	5/4/93	Boissonneault et al.	514	178	
	62.	5,210,081	5/11/93	Raveendranath et al.	514	179	
	63.	5,262,408	11/16/93	Bergink	514	182	
	64.	5,276,022	1/4/94	Casper	514	179	
	65.	5,280,023	11/8/94	Ehrlich et al.	514	177	
	66.	5,288,717	2/22/94	Raveendranath et al.	514	179	
	67.	5,362,720	11/8/94	Labrie	514	169	
	68.	5,382,573	1/17/95	Casper	514	170	
	69.	5,418,228	5/23/95	Bennink	514	182	
	70.	5,434,146	7/18/95	Labrie et al.	514	169	
	71.	5,464,871	11/1995	Kun et al.	514	617	
	72.	5,510,342	4/23/96	Washburn et al.	514	179	
	73.	5,541,172	7/30/96	Labrie	514	169	
	73.	5,545,634	8/13/96	Labrie	514	169	
	75.	5,547,948	8/20/96	Barcomb	514	170	
	76.	5,567,695	10/22/96	Labrie	514	169	
	77.	5,629,303	5/13/97	Labrie et al.	514	169	

EXAMINER _____
 *EXAMINER _____

DATE CONSIDERED _____

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)					Attorney Docket Number: 8789-16CT		Serial No. to be assigned	
					Applicants: Hill et al.			
					Filing Date: concurrently herewith			Group to be assigned
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
	78.	5,654,011	8/5/97	Jackson et al.	424	635		
	79.	5,753,639	5/19/98	Labrie	514	169		
	80.	5,759,576	6/2/98	Barcomb	424	479		
	81.	5,759,577	6/2/98	Barcomb	424	479		
	82.	5,807,586	9/15/98	Jackson et al.	424	630		
	83.	5,846,960	12/8/98	Labrie	514	169		
	84.	5,861,387	1/19/99	Labrie et al.	514	169		
	85.	5,861,431	1/19/99	Hildebrand et al.	514	557		
	86.	5,908,638	6/1/99	Huber et al.	424	465		
	87.	5,998,639	12/7/99	Raijmakers, et al.	552	625		
	88.	Re. 36,247	7/6/99	Plunkett et al.	514	170		
	89.	6,040,333	3/21/00	Jackson	514	456		
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Subclass	Translation Yes No	
	92.	IL25265	12/31/69	Israel			X (Abstract only)	
	91.	1214712	12/2/70	Great Britain				
	92.	DT2431694 A1	3/4/76	Germany			X	
	93.	DT2624025 A1	12/9/76	Germany			X	
	94.	1561244	2/13/80	Great Britain				
	95.	GB2096462A	10/20/82	Great Britain				
	96.	DE3341638 A1	11/17/83	Germany			X (Abstract)	

 EXAMINER _____
 *EXAMINER

DATE CONSIDERED _____

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)		Attorney Docket Number: 8789-16CT	Serial No. to be assigned
		Applicants: Hill et al.	
		Filing Date: concurrently herewith	Group to be assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	97.	Andreolini, et al., <i>Estrogen Conjugates in Late-Pregnancy Fluids: Extraction and Group Separation by a Graphitized Carbon Black Cartridge and Quantification by High-Performance Liquid Chromatography</i> , Anal. Chem. 59 :1720-1725 (1987).	
	98.	Fujino, et al., <i>3-(Difluoro-1,3,5-trianinyl)-1-(ethylthio)-2-n-propylbenz[f]isoindole as a Fluorescence Derivation Reagent for Estrogens in High-Performance Liquid Chromatography</i> , Chem. Pharm. Bull., 37 (7): 1939-1940 (1989).	
	99.	Vest, Floyd B. & Karnes, H. Thomas, <i>Luminescent Derivation of Estrogens for HPLC Detection</i> (Abstract), Department of Pharmacy and Pharmaceutics, Medical College of Virginia, APQ 1198.	
	100.	Takadate, et al., <i>A Convenient Derivatization with Anion Exchange Resin Catalysts for High-Performance Liquid Chromatographic Analysis. I. Derivatization of Estrogens with Dansyl Chloride</i> , Chem. Pharm. Bull., 33 (11): 5092-5095 (1985).	
	101.	Novakovic, et al., <i>High-Performance Liquid Chromatographic Determination of Equine Estrogens with Ultraviolet Absorbance and Electrochemical Detection</i> , Journal of Chromatography A, 678 : 359-363 (1994).	
	102.	Townsend, et al., <i>High-Performance Liquid Chromatographic Determination of Conjugated Estrogens in Tablets</i> , Journal of Chromatography, 450 : 414-419 (1988).	
	103.	Ishida, et al., <i>Determination of Oestrogens in Pregnancy Urine by High-Performance Liquid Chromatography with Fluorescence Detection</i> , Journal of Chromatography, 431 : 249-257 (1988).	
	104.	<i>Conjugated Estrogens</i> , The United States Pharmacopeia (USP), published by United States Pharmacopeial Convention, Inc., pp. 627-629 (2000).	
	105.	Synthetic Generic Conjugated Estrogens: Timeline, May 5, 1997, < http://www.fda.gov/cder/news/cetimeline.htm >.	
	106.	FDA Statement on Generic Premarin, HHS News Press Release, P97-12, May 5, 1997, < http://www.fda.gov/cder/cepressrelease.htm >.	
	107.	New Drug Approval for Cenestin, Synthetic Conjugated Estrogens, A: March 24, 1999, <i>Questions and Answers</i> , < http://www.fda.gov/cder/news/cenestin/qa.htm >.	
	108.	NDA 20-992 Cenestin™ (synthetic conjugated estrogens, A) Tablets Physicians Package Insert, pp. 1 - 10 (1999).	
	109.	NDA 20-992 Cenestin™ (synthetic conjugated estrogens, A) Tablets Patient Package Insert, pp. 11 - 13 (1999).	
	110.	FDA Backgrounder on Conjugated Estrogens, May 5, 1997, < http://www.fda.gov/cder/cebackground.htm >.	
	111.	Letter from Yana Ruth Mille, Chief, Compndial Operations Staff, HFD-354, Office of Pharmaceutical Science, Center for Drug Evaluation & Research to Joseph G. Valentino, J.D., Senior Vice President and General Counsel, The United States Pharmacopeial Convention, Inc. (March 8, 2000) (REF: 3-00-001-O).	

 EXAMINER
 *EXAMINER

DATE CONSIDERED

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)		Attorney Docket Number: 8789-16CT	Serial No. to be assigned
		Applicants: Hill et al.	
		Filing Date: concurrently herewith	Group to be assigned
	112.	Letter from Yana Ruth Mille, Chief, Compendial Operations Staff, HFD-354, Office of Pharmaceutical Science, Center for Drug Evaluation & Research to Joseph G. Valentino, J.D., Senior Vice President and General Counsel, The United States Pharmacopeial Convention, Inc. (March 8, 2000) (REF: 3-00-002-O).	
	113.	Memorandum from Janet Woodcock, M.D., Director, Center for Drug Evaluation & Research to Douglas L. Sporn, Director, Office of Generic Drugs, regarding Approvability of a Synthetic Generic Version of Premarin (May 5, 1997).	
	114.	Sakac, Marijan N. et al., "Chemical Behavior of 3, 17.beta.-dipropionoxy-9.alpha.-hydroxyestra-1,3,5(10)-trien-6-one," <i>DATABASE CHEMABS 'ONLINE'</i> , Database accession no. 128:180573 XP002171996, J. Serb. Chem. Soc., 63 (1): 21-24 (1998).	
	115.	Wiese, Thomas et al., "Induction of the Estrogen Specific Mitogenic Response of MCF-7 Cells by Selected Analogues of Estradiol-17 β : A 3D Study," <i>Journal of Medicinal Chemistry</i> , 40 (22): 3659-3669 (1997).	
	116.	Yang et al., "The Hydroxylation and Amidation of Equilenin Acetate Catalyzed by Chloro[5,10,15,20-tetrakis(pentafluorophenyl)porphyrinato]manganese(III)," <i>Chem. Commun.</i> , 7 : 531-532 (2000).	
	117.	Yang, Jerry et al., "Regioselective Oxidations of Equilenin Derivatives Catalyzed by a Rhodium(III) Porphyrin Complex-Contrast with the Manganese(III) Porphyrin," <i>Tetrahedron Letters</i> , 41 (42): 8063-8067 (2000).	
	118.	International Search Report corresponding to PCT/US 01/07544; mailed on August 6, 2001	
	119.	Rzheznikov, V. M. et al., "Synthesis and Biological Activity of Estrone 8-iso- and D-homoanalogs Oxidized for Rings B and C," <i>DATABASE CHEMABS 'Online'</i> , Database accession no. 110:108353 XP002171997, Khim.-Farm. Zh. 22 (12): 1462-1465 (1988).	
	120.	Sakac, Marija N. et al., "Synthesis of New Steroidal N-butyl-N-methyl-undecanamide Derivatives," <i>DATABASE CHEMABS 'Online'</i> , Database accession no. 133:335378 XP002171995, ZB. MATICE SRP. PRIR. NAUKE 96 : 5-9 (1999)	
	121.	Center for Drug Evaluation and Research (CDER), Guidance for Industry, Draft Guidance, <i>Conjugated Estrogens, USP - LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence</i> , March 2000, < http://www.fda.gov/cder/guidance/index.htm >.	
	122.	Physician's Desk Reference, 53 : 3367-3379 (1999).	

EXAMINER

DATE CONSIDERED

*EXAMINER

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.